REMARKS

Status of the Claims

The status of the claims is as follows:

- Claims 34-38, 41-44, 85, 86, 95-98, 110-114, 123-132 and 136-143 are all pending.
- Claims 34, 43, 95, 123 to 129 and 131 are amended.
- Claims 39, 40, 45-94, 99-109 and 115-122 are canceled.
- Claims 44, 85, 86, 96, and 98, 133-135 are withdrawn.
- Claims 137-146 are new.

Claims 34-38, 41-43, 95, 110-114 and 123-26 have been rejected under 35 USC 112, first paragraph for not reasonably providing enablement for a method of detecting steroid hormone-like cancer growth stimulation by a subject of interest. These claims have also been rejected under 35 USC 112, first paragraph for lack of written description support for the anti-steroid, secretory immunoglobulins.

Claims 124, 127 and 129-135 have been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 123, 125, 126 and 128 have been rejected under 35 USC 112, first paragraph as failing to comply with the written description.

Claims 123, 125, 126 and 128 have been rejected under 35 USC 112, first paragraph, because the specification does not enable any person skilled in the art to use the invention.

The inventor acknowledges and thanks the Office for the withdrawal of the previous objections and rejections (Office Action Points 6 to 15).

Lack of Enablement and Lack of Written Description (Office Action Points 16 and 17)

The applicant understands the office action of 12/4/09 to say that the instant specification demonstrates that IgM and IgA provide negative regulation of steroid hormone responsive mucosal epithelial cancer cells. While applicant takes exception to

the enablement and written description rejections applied to the claims, the applicant acknowledges the Examiner's arguments, and for the sake of proceeding with the prosecution of this application, the applicant has amended the claims to specify that the cancer cells are hormone responsive mucosal epithelial cancer cells. However, the applicant reserves the right to pursue in later related applications the more broadly claimed invention in general.

Thus, claims 34, 43, 95, 123, 125, 126, 128, 129 and 131 have been amended to specify that the cancer cells of the claims are hormone responsive mucosal epithelial cancer cells. Support for these cancer cells is acknowledged in the current office action. For example, in the outstanding office action on p.11, first paragraphs, it is stated that "The specification demonstrates IgA and IgM provide negative regulation of steroid hormone responsive mucosal epithelial cancer cell growth (P. 15, para 0030)." Thus, the claims now specify that the cancer cells are hormone responsive mucosal epithelial cancer cells as provided in the written description.

Identifying the particular type of cancer cells that are inhibited by the named immunoglobulins that are described in detail in the written description will allow a person of ordinary skill in the art to practice this aspect of the claimed invention. Therefore, the applicant respectfully requests that the rejections under 35 USC 112 First Paragraph for non-enablement and lack of written description be withdrawn.

Indefiniteness Rejection (Office Action Point 18)

a) Claims 124 and 127 are asserted to be indefinite for the recitation "thyroid hormone." The references to thyroid hormone are removed from the claims, so the rejection is now moot.

b) Claims 129 and 130 are asserted to be indefinite for the recitation of the phrase "steroid hormone-dependent cell growth stimulating effect by said substance of interest" with out the presence of a steroid substance in the medium. As described in the preamble of claim 129, the purpose of the test is to "detect steroid hormone cancer cell growth stimulation by a substance of interest." Thus, the presence of the

substance of interest will provide the steroid hormone-dependent cell growth stimulating effect if the substance of interest has properties of a steroid hormone. Thus to determine if the substance of interest will promote cell growth, other factors such as an amount of steroid hormone to promote growth should not be present, so that the claim as written is not indefinite. Therefore, the applicant respectfully requests the rejection for indefiniteness be withdrawn.

c) Claims 131 and 132 are asserted to be indefinite for the recitation of the phrase "estrogen hormone-dependent cell growth stimulating effect by said substance of interest" with out the presence of an estrogen in the medium. As described in the preamble of claim 131, the purpose of the test is to "detect estrogen cancer cell growth stimulation by a substance of interest." Thus, the presence of the substance of interest will provide the estrogen-dependent cell growth stimulating effect if the substance of interest has properties of an estrogen or acts like an estrogen mimic. Thus to determine if the substance of interest will promote cell growth, other factors such as an amount of estrogen to promote growth should not be present, so that the claim as written is not indefinite. Therefore, the applicant respectfully requests the rejection for indefiniteness be withdrawn.

d) Claims 133-135 are indefinite for reciting steps for making the steroid hormone depleted serum when the elected invention is a screening method. These claims have been withdrawn, so the rejection is now moot.

e) and f) Claim 135 is withdrawn, so these rejections are now moot.

Failing to Comply with the Written Description (Office Action point 19)

Claims 123, 125, 126 and 128 are asserted to fail to comply with the written description requirement, a new matter rejection. These claims recited reference to the cell line MCF-K, which was not found in the written description. The cell line should have been MCF-7K, which is included in the written description, thus these claims are amended to recite MCF-7K instead of MCF-K. Support for MCF-7K can be found at least on page 40, Table 1 in the original specification. Therefore, this is not new matter, and the applicant respectfully requests that the rejection be withdrawn.

Lack of Enablement, Biological Deposit (Office Action point 20)

Claims 123, 125, 126 and 128 are asserted to lack enablement because the specification does not provide evidence that the claimed biological materials are (a) known and readily available to the public; (b) reproducible from the written description. Cell line MCF-7A is available from the ATCC, as MCF-7, the A appended to the name to indicate the cell line is from the ATCC, and cell line MCF-7K is available from the Karmanos Cancer Center, Cell Line Repository (KCC) as the MCF-7, the K appended to the name to indicate that the cells were obtained from the KCC. This is indicated in footnote 1 of Table 1, page 40 that there are two strains of MCF-7, one from ATCC and one from KCC, and from the listed reference material.

Cell lines H-301 and MTW9/PL2 are available from the inventor's company and are thus readily available to the public and have been described in publications *In Vitro Cell Dev Biol* **24**, 42-52 (1988) (MTW9/PL2) and *Endocrinology* **98**, 1260-72 (1976) (H-301) and are thus known. These cell lines have already been supplied to other researchers thus showing that these cell lines are known and available to the public. This supplying is substantiated in the publication *In Vitro Cell Dev Biol* **24**, 42-52 (1988) on page 432, "The magnitude of the estrogenic effect with H-301 cells was equal to that reported by others studying this line in cultures supplemented with CDE serum (Soto et al., 1988)," and in the corresponding reference: Soto, A. M.; Bass, J. C.; Sonnenschein, C. "Proliferative behavior of the cloned Syrian hamster tumor cells H301," *Cancer Res.* **48**, 3676-3680 (1988). The MPEP at 2404.01 states " [h]owever, the mere fact that the biological material is commercially available only through the patent holder or the patent holder's agents or assigns shall not, by itself, justify a finding that the necessary material is not readily available, absent reason to believe that access to the biological material would later be improperly restricted." Thus, the cells are known and readily available to the public.

New Claims

No new matter is added. Support for the new claims137-144 can be found at least in the specification in Example 5 on pages 36 – 37 (Including RM Evans citation supporting common mechanisms of steroid and thyroid hormones) and Figures 22, 23, and 24; Example 10 on pages 45 – 49 (Thyroid hormones presented on page 48), Table 7 shows Serum-free Media Compositions that contain thyroid hormones as critical components supporting Mucosal Cancer Cell Growth, and Figures 43 and 44 that show thyroid hormone alone and again as a component of a serum-free medium; Example 21 on page 68 and Figures 105 – 120 that show assays in medium PCM-9 containing growth promoting concentrations of thyroid hormone plus and minus growth inhibiting concentrations of IgA and IgM (the studies demonstrate that thyroid hormone growth effects are inhibited by these immunoglobulins with responsive cells); and page 134, paragraph [0496] stating that "this demonstrates that colonic cancer cells respond to thyroid hormones in the same manner that ER^+ cells respond to E_2. Estrogens and thyroid hormones belong to the same superfamily of receptors and both are required for normal physiologic growth and development." The claims are similar to the previous claims for testing for cancer growth stimulating effect of a substance of interest, but the cancer cell lines are thyroid hormone responsive instead of steroid hormone responsive.

New claims 145 and 146 select a single option of their respective independent claim, so no new matter is added.

Conclusion

The Office acknowledged in earlier office actions that the specification teaches that the instant specification satisfies the long-felt needs for a sensitive way to screen substances for estrogenic and androgenic effects. The office also acknowledges that the specification teaches that since the early 1980's researchers have unsuccessfully tried to identify serum-borne inhibitors of steroid responsive cell growth and despite its first proposal more than fifteen years ago, the purified steroid reversible serum-borne inhibitor had not been previously described. The office also acknowledges that the specification teaches that for the first time it is disclosed that, surprisingly, certain immunoglobulins exert a steroid hormone reversible negative regulatory effect on mucosal epithelial cancer

cell growth. These immunoglobulin inhibitors have many immediate and potential applications as reagents for cell growth assays. The claimed method is useful for identifying substances that have unrecognized hormone-like properties that present health hazards.

Thus, as acknowledged by the office, the specification teaches that there was a long felt need in this arena and the results are surprising for the material described in the specification, especially with regard to certain immunoglobulins acting as inhibitors. Also, the Office acknowledges that assays based on the findings in the specification are useful; these are the assays of the present application. The claims have now been amended so that the claims are fully supported by the specification. Therefore, the applicant respectfully puts forward that the claims are now patentable, and in condition for allowance.

In view of the above amendments and remarks, the Examiner is requested to pass the case to issue. Should the Examiner have any comments or suggestions that might facilitate the prosecution of this application, the Examiner is requested to contact the undersigned representative by telephone.

Respectfully submitted,

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